

### REMARKS

Claim 103 has been cancelled, and claims 85-91 and 93-102, and 104-110 are pending by the current amendment. Consideration of the remarks below is respectfully requested.

#### Claim Rejections

##### Rejections Under 35 U.S.C. §112, First Paragraph – Written Description

Claims 103 and 104 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description support in the specification. Applicant respectfully traverses.

As a preliminary matter, Applicant points out that claim 103 has been cancelled, without admission or disclaimer.

The Office Action expresses that support is not found in the specification for the recitation in claim 104 that nucleic acid is not substantially degraded after exposure of the claimed particles to serum for 30 minutes at 37°C. The Office Action further contends that Example 10 provides inadequate support for claim 104. Applicant respectfully disagrees.

Beginning at page 71, line 4, the specification describes the time course experiment used to determine and compare the stabilities of free and encapsulated nucleic acids in serum. As stated in the specification, aliquots of free or encapsulated nucleic acids exposed to serum, as well as aliquots of control encapsulated nucleic acid samples including 0.5% Triton X100 and lacking serum, were taken at various time points. At page 70, line 7, the specification states that free phosphorothioate oligonucleotide showed significant breakdown within 30 minutes. Further, at page 70, line 8, the specification states that encapsulated phosphorothioate oligonucleotide did not show any sign of degradation even after 24h incubation in serum (emphasis added). Applicant submits that these excerpts clearly convey to one of skill in the art that nucleic acid aliquots were taken at 30 minutes in this time course assay at which point encapsulated phosphorothioate oligonucleotide was not degraded (indeed, was not significantly degraded even after 24h) whereas non-encapsulated phosphorothioate oligonucleotide was significantly degraded. Accordingly, Applicant submits that the specification fully supports claim 104 directed to a nucleic acid-lipid particle wherein the nucleic acid is not substantially degraded after incubation of the particle in serum at 37°C for 30 minutes. Withdrawal of the rejection and allowance of claim 104 is respectfully requested.

#### Obviousness-type Double Patenting Rejections

##### U.S. Patent No. 6,858,225

Claims 85-91, 93, 97-106, and 108-110 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,858,225 in view of Collins (U.S. Patent No. 6,355,267) and Cullis et al. (U.S. Patent No. 6,417,326) and Wheeler et al. (WO 96/40964). Claims 94-96, and 107 stand rejected in further view of Unger et al. (U.S. Patent No. 6,143,276) and Wheeler et al. (U.S. Patent No. 6,586,410).

Applicant points out that claim 103 has been cancelled, without admission or disclaimer. Applicant submits herewith a terminal disclaimer, obviating the rejection of the remaining pending claims.

U.S. Patent No. 6,287,591

Claims 85-91, 93, 94, 97-106, and 108-110 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent No. 6,287,591 in view of Collins (U.S. Patent No. 6,355,267) and Cullis et al. (U.S. Patent No. 6,417,326). Claims 95, 96, and 107 stand rejected in further view of Wheeler et al. (U.S. Patent No. 6,586,410).

Applicant points out that claim 103 has been cancelled, without admission or disclaimer. Without addressing the propriety of the rejection, Applicant submits herewith a terminal disclaimer, obviating the rejection of the remaining pending claims.

**CONCLUSION**

Applicant respectfully submits that all pending claims of the present application satisfy the requirements for patentability and are in condition for allowance. Early indication of the same is therefore respectfully requested.

If a telephone call will help expedite any aspect of the prosecution of the instant application the Examiner is encouraged to contact the undersigned at 415-781-1989, or by facsimile at 415-398-3249.

Respectfully submitted,  
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